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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/785,274

02/24/2004

Shang-Tian Yang

OSU 0003

3860

PA/41096.8/011D8

7590

06/23/2006

EXAMINER

LILLING, HERBERT J

DINSMORE & SHOHL LLP

One Dayton Centre

Suite 500

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Dayton, OH 45402-2023

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,274

Applicant(s)

YANG ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

1. Receipt is acknowledged of the prior art information disclosure statements filed May 28, 2004.

2. Claims 1-40 are present in this instant application.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-36, drawn to a process for preparing a multilayer enzyme immobilized onto a fibrous matrix, classified in class 435, subclass 175.
- II. Claim 37, drawn to a process for the production of galactooligosaccharides employing a multilayer immobilized enzyme fibrous product of claim 1 with lactose, classified in class 435, subclass 101.
- III. Claim 38, drawn to a process of employing a multilayer immobilized enzyme fibrous product of claim 1 for the hydrolysis of lactose to form glucose and galactose, classified in class 435, subclass 100.
- IV. Claims 39-40, drawn to a fibrous-bed biocatalytic reactor for the production of galacto-oligosaccharides from or the hydrolysis of lactose comprising a fibrous matrix containing (a) multilayer immobilized polyethyleneimine-enzyme aggregates prepared by process claim 1, classified in class 435, subclass 283.1+.

4. The inventions are independent or distinct, each from the other because:

Invention I process does not require the specifics of Invention II or Invention III. The processes are distinct from each other since Invention II does not require the specific process of Invention I to prepare the product per se which can be made by another and materially different process. Inventions I and II/III are related as process of preparing a product and further a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the process product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the processes are drawn to different uses in different processes classified in different areas.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

5. In addition, a search and examination for the multiple inventions would involve an extremely burdensome search in view of the divergent searches for the claimed subject matter as well as searches in different classifications for the different inventions.

Claims 1 and 37-40 are generic to the following disclosed patentably distinct species:

A. Whereby the enzyme is selected from

- a. B-galactosidase;
- b. lipase;
- c. lactate dehydrogenase;
- d. formate dehydrogenase ;
- e. glucose isomerase ;
- f. combinations thereof-please specify the combination.

B. Whereby the fibrous matrix is selected from:

- a. cotton fibers;
- b. poly(ethylene terephthalate);
- c. glass fiber;
- d. wool;
- e. carbon fiber;
- f. ceramic fiber ;
- g. paper;
- h. rayon;
- i. combination thereof-please specify the combination.

C. Whereby the Apparatus is for the production of:

- a. galacto-oligosaccharides;
- b. hydrolysis of lactose to glucose.

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The species are independent or distinct because each of the above A, B or C is drawn to different species requiring different substrates as well as processing conditions e.g., both C a and Cb have the same flow agent containing lactose solution but two totally different products are formed. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include:

(i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143);

and

(ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. In accordance with the this Tech Center for rejoinder of non-elected claims as follows:

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

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subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

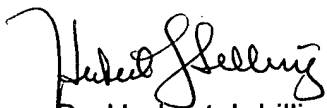
9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL
(571) 272-0918
Art Unit 1651
June 19, 2006


Dr. Herbert J. Lilling
Primary Examiner
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